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Magers

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[54] **COMPOSITION AND METHOD OF ASSAYING FOR KETONE BODIES**

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Related U.S. Application Data

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[58] **Field of Search** 435/26, 25, 14, 435/4; 436/128, 904, 119, 63, 74

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[57] **ABSTRACT**

A composition, test device and method of determining the presence or concentration of ketone bodies, and specifically D-β-hydroxybutyrate, in a test sample are disclosed. The test device includes a test pad comprising a suitable carrier matrix incorporating an indicator reagent composition capable of interacting with D-β-hydroxybutyrate to produce a detectable or measurable response. In addition, a new and improved indicator reagent composition, comprising a) an indicator dye that is responsive to thiols, such as a substituted isobenzothiazolone, Ellman's reagent or a derivative of Ellman's reagent; b) D-β-hydroxybutyrate dehydrogenase; c) lipoamide dehydrogenase; d) D,L-lipoamide; and e) nicotinamide adenine dinucleotide, is incorporated into the carrier matrix to provide an accurate and sensitive assay of a test sample for D-β-hydroxybutyrate (DHBA) in particular, and for ketone bodies in general. The improved method and composition are especially useful in the assay of whole blood, blood serum, blood plasma and urine for ketone bodies.

29 Claims, 14 Drawing Sheets